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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Timothy S Corder  
Vinson & Elkins  
2300 First City Tower  
1001 Fannin Street  
Houston, TX 77002-6760

EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,922

Applicant(s)

GAYED, ATEF

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**CLAIMS 1-7 AND 10-53 ARE PRESENTED FOR EXAMINATION**

Applicant's Response filed May 3, 2004 has been received and entered into the application.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

*I* Claims 1-7, 10-39, 45, 48, 51 and 53-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 33, 45, 48 and 51, the metes and bounds of the expression "is not formulated for topical administration" are unclear. Neither the claim nor the specification provides a standard for ascertaining the requisite qualitative characteristic of the formulation in order to determine whether it was "formulated for topical administration" or not. Lacking such standard, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Such a lack of uncertainty would exist, for example, where the formulation was merely one that contained an active ingredient, the claimed preservatives and water. Clear, such a formulation could be applied topically, but it would also be capable of being administered by routes other than topically, such as orally. Lacking a definite limitation as to what elements are intended to be encompassed by the present formulations and which are not, it is believed the claims are indefinite as per 35 U.S.C. 112, second paragraph.

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**II** Claims 1-7, 10-39, 45, 48, 51 and 53-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term “the composition is not formulated for topical administration” in claims 1, 33, 45, 48 and 51 is accepted to mean that the so formulated composition is not be used in a topical manner. However, this meaning does not appear to be applicant’s intent as evinced by claims 31, 32 and 37 where the topical formulation/routes including a cream, an inhalant, an aerosol, a gel, an ointment, a suppository, a powder, via mucosa, by suppository, by inhalation, aurally, or ocularly are set forth. Compare with the meaning of topical as set forth in the Remington’s reference cited by applicant at page 712, col. 1, under the heading “Topical Route”, i.e., “Topical administration is employed to deliver a drug at, or immediately beneath, the point of application...[a] large number of topical drugs are applied to the skin, although topical drugs are also applied to the eye, nose and throat, ear, vagina, etc.”.

***Claim Rejection - 35 USC § 103***

Claims 1, 2, 16, 29, 31-34, 37-44 and 45-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bergamini et al., (U.S. Patent No. 5,597,560), already of record, for the reasons of record as set forth in the previous Office action .

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Applicant's amendments and arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicant has argued that the expression "the composition is not formulated for topical administration" is not merely a statement of intended use, but an actual material limitation because those skilled in the art would recognize that formulation of compositions would depend upon the route by which a particular formulation is administered. In response thereto, the Examiner still believes that the above phrase carries with it a degree of intent such that the claims fail to distinguish over the compositions of Bergamini et al.

While it is acknowledged that Bergamini et al. only teaches ocular and aural administration, it is not seen that the compositions taught by Bergamini et al. could not also be suitable for oral administration. Because composition claims are currently pending, the question is not by what administration route does the prior art teach for the composition, but rather what components are taught to be contained in the composition and how does such a composition differ, if at all, from the components required by applicant's composition. The Examiner maintains that the difference would have been, at least, an obvious difference.

Also, claims 31, 32, 37, 40, 46 and 49 clearly contain recitations of topical dosage forms/routes of administration that are clearly taught or otherwise suggested by Bergamini et al., i.e., including liquids, solutions, mixtures, emulsions, suspensions, gels, creams, ointments, aurally and ocularly.


None of the claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

June 14, 2004